

Date: 29-12-2022  
Effective Date: 29-12-2022

## Certificate of Calibration

**Customer Name:** **REDCLIFFE LIFETECH PVT. LTD. BILASPUR**

**Model :** **Automated Hematology Analyzer Elite 580**

**Serial No. :** **K11052128082**

**Calibration Done Date:** **29/12/2022**

**Next Calibration Due Date On or Before:** **28-12-2023**

**Lab In-charge: .** **SAJAN SONVANI**

*This is to certify that the above-mentioned product has been verified of calibration for CBC 5 parameters (WBC, RBC, HGB, MCV and PLT) according to the standard procedures provided by Erba Lachema s.r.o, Karasek.*

Calibration at site performed by

Engineer Name - AVINASH   
Designation - APPLICATION MANAGER  
Transasia Bio-Medicals Ltd

Encl:

1. Certificate of Inspection
2. Assay Sheet of Hematology Calibrator (H Cal)
3. Printouts
4. Traceability Document

Date: 29/12/2022  
Effective Date: 29/12/2022

## Certificate of Inspection

1. Model: Automated Hematology Analyzer Elite 580
2. Serial No.: K11052128082
3. Calibration Date: 29/12/2022
4. Material used: H Cal (Lot No. PLUS1222, Expiry date: 10-Jan-2023)

By comparing your data to the results of the standard counters in Erba Lachema, the calibration for CBC 5 parameters using the measurement standard material (H Cal) was completed. The calibration result of 5 runs is summarized in the following table. Please refer to the attached sheets for the details.

Technical Service Department  
Transasia Bio-Medicals Ltd

# Calibrator

Lot No.: PLUS1222  
Calibration Mode: Whole Blood

Exp. Date: 2023/01/10  
Print Time: 2022/12/29 15:58:35

PARA.	WBC	RBC	HGB	MCV	PLT	MPV
Target	9.13	4.52	13.9	87.6	253	
1	9.53	4.60	14.0	88.9	260	
2	9.29	4.55	13.9	88.9	281	
3	9.37	4.50	14.0	89.1	284	
4	9.34	4.55	13.8	88.6	280	
5	9.53	4.58	14.0	88.9	278	
6	9.30	4.60	14.0	89.0	267	
7	9.52	4.57	14.1	88.9	267	
8	9.51	4.56	14.0	89.2	256	
9	9.55	4.55	14.0	88.9	253	
10	9.77	4.61	14.0	89.2	263	
11	9.50	4.60	14.0	88.9	251	
12	9.77	4.60	14.0	89.0	253	
CBC-Mean	9.393	4.563	13.95	88.90	275.0	
DIFF-Mean	9.603	4.582	14.02	89.02	257.2	
CBC-CV(%)	1.2	0.8	0.6	0.2	3.4	
DIFF-CV(%)	1.4	0.5	0.3	0.2	2.5	
CBC Cal. Coefficient(%)	97.20	99.06	99.64	98.54	92.00	
DIFF Cal. Coefficient (%)	95.07	98.65	99.14	98.40	98.37	
Transfer Coefficient	1.0224	1.0042	1.0050	1.0014	0.9352	

# Hematology Analysis Report

First Name:

Sample Type:

Sample ID: background

Last Name:

Department:

Run Time: 2022/12/29 07:51

Gender:

Patient ID:

Diagnosis:

Age:

Parameter	Result	Ref. Range	Unit	Parameter	Result	Ref. Range	Unit
1 WBC	0.02 ↓		10 <sup>3</sup> /uL	16 P-LCC	****		10 <sup>9</sup> /L
2 RBC	0.00 ↓		10 <sup>6</sup> /uL				
3 HGB	0.0 ↓		g/dL				
4 HCT	0.0 ↓		%				
5 MCV	****		fL				
6 MCH	****		pg				
7 MCHC	****		g/dL				
8 RDW-CV	****		%				
9 RDW-SD	****		fL				
10 PLT	0 ↓		10 <sup>3</sup> /uL				
11 MPV	****		fL				
12 PDW-SD	****		fL				
13 PDW-CV	****		%				
14 PCT	****		%				
15 P-LCR	****		%				

Sample Type:

Microscopic exam. Time:

Description:

Submitter:

Operator: admin

Approver:

Sampling Time: 2022/12/29 07:51

Delivery Time: 2022/12/29 07:51

Validated Time:

Report Time: 2023/01/15 11:21

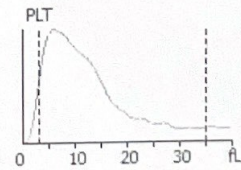
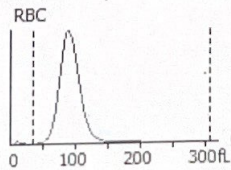
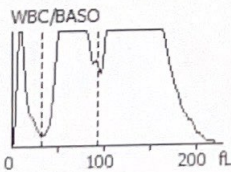
Remarks:

**\*The Report is responsible for this sample only. If you have any questions, please contact us in 24 hours.**

# L-J QC Analysis

File No.: 5                                      Lot No.: EH2211N                                      Level: Normal  
 Operator: admin                                      Exp. Date: 2023/01/20                                      Run Time: 2022/12/29 16:16  
 Print Time: 2022/12/29 16:18                                      QC Mode: Whole Blood-CBC+DIFF                                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>8.82</b>	<b>6.90-8.90</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	60.8	50.0-66.0	%
3 Lym%	27.6	21.7-37.7	%
4 Mon%	6.4	1.4-11.4	%
5 Eos%	5.2	0.0-10.4	%
6 Bas%	70.2	63.2-79.2	%
7 Neu#	5.37	4.20-5.60	10 <sup>3</sup> /uL
8 Lym#	2.44	1.60-3.00	10 <sup>3</sup> /uL
9 Mon#	0.56	0.00-1.00	10 <sup>3</sup> /uL
10 Eos#	0.45	0.00-0.80	10 <sup>3</sup> /uL
11 Bas#	6.19	5.30-6.70	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>4.74</b>	<b>4.32-4.80</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	14.2	↑ 12.9-14.1	g/dL
14 HCT	42.6	↑ 35.5-42.5	%
15 MCV	89.8	80.5-90.5	fL
16 MCH	30.1	26.2-31.2	pg
17 MCHC	33.5	30.5-36.5	g/dL
18 RDW-CV	16.5	14.5-20.5	%
19 RDW-SD	55.4	42.3-62.3	fL
<b>20 PLT</b>	<b>243</b>	<b>180-260</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.9	7.0-13.0	fL
22 PDW-SD	11.1	9.9-15.9	fL
23 PDW-CV	16.0	13.6-19.6	%
24 PCT	0.241	0.135-0.335	%
25 P-LCR	25.5	19.8-35.8	%
26 P-LCC	62	42-92	10 <sup>9</sup> /L

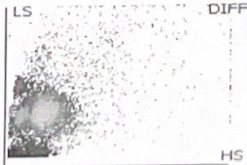
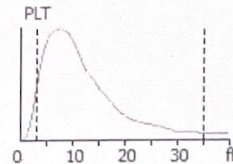
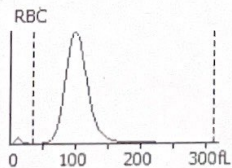
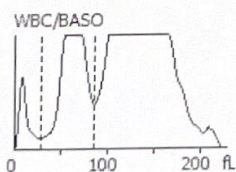


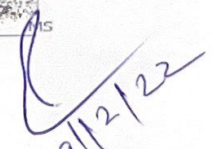
29/12/22

## L-J QC Analysis

File No.: 4                      Lot No.: EH2211H                      Level: High  
 Operator: admin                      Exp. Date: 2023/01/20                      Run Time: 2022/12/29 16:15  
 Print Time: 2022/12/29 16:16                      QC Mode: Whole Blood-CBC+DIFF                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>18.64</b>	<b>15.07-20.07</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	69.4	58.7-72.7	%
3 Lym%	18.0	14.3-26.3	%
4 Mon%	6.7	0.8-12.8	%
5 Eos%	5.9	0.2-14.2	%
6 Bas%	81.9	72.3-88.3	%
7 Neu#	12.94	10.14-12.94	10 <sup>3</sup> /uL
8 Lym#	3.36	2.47-4.67	10 <sup>3</sup> /uL
9 Mon#	1.25	0.09-2.29	10 <sup>3</sup> /uL
10 Eos#	1.09	0.00-2.54	10 <sup>3</sup> /uL
11 Bas#	15.26	13.50-16.50	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>5.25</b>	<b>4.68-5.68</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	17.6	8.7-24.7	g/dL
14 HCT	52.7	45.7-53.7	%
15 MCV	100.4	89.9-101.9	fL
16 MCH	33.6	29.8-34.8	pg
17 MCHC	33.4	30.7-36.7	g/dL
18 RDW-CV	16.7	13.8-19.8	%
19 RDW-SD	62.5	44.1-68.1	fL
<b>20 PLT</b>	<b>447</b>	<b>417-537</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.4	7.1-13.1	fL
22 PDW-SD	10.8	9.7-15.7	fL
23 PDW-CV	15.7	13.3-19.3	%
24 PCT	0.421	0.282-0.682	%
25 P-LCR	22.8	18.8-34.8	%
26 P-LCC	102	93-163	10 <sup>9</sup> /L



  
 29/12/22

# ELite H CAL



Hematology Calibrator / Hematologický kalibrátor / Calibrador de hematología

## Assay values

Atestované hodnoty / Valores de la media

**LOT**

PLUS1222



2023-01-10

Name Název Nombre	Cat. No. Kat. č. No.Cat.	Package volume Objem balení Volumen
ELite H CAL	HEM00027	3 ml



Before using refer to the instruction sheet for mixing directions. Calibration errors may result if instructions are not followed exactly.

Před použitím čtěte návod. Nepřesný postup kalibrace může způsobit chybné výsledky stanovení.

Lea las instrucciones de mezclado antes de usar. Los errores de calibración pueden surgir si no se siguen las instrucciones exactamente.

Instrument Analyzátor Instrumento	Parameter Analyt Analito	Unit Jednotka Unidad	Assigned Value Hodnota Valor	Deviation Odchyłka Desviación
<b>ELite 580</b> (SW A10.4 or higher)	WBC	$\times 10^9/L$	9.13	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.52	$\pm 0.08$
	HGB	g/L	139	$\pm 2$
		g/dL	13.9	$\pm 0.2$
	MCV	fL	87.6	$\pm 2.0$
	PLT	$\times 10^9/L$	253	$\pm 12$
<b>H560</b> (SW A12.2 or higher; version A only)	WBC	$\times 10^9/L$	8.87	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.59	$\pm 0.08$
	HGB	g/L	138	$\pm 2$
		g/dL	13.8	$\pm 0.2$
	MCV	fL	88.5	$\pm 2.0$
	PLT	$\times 10^9/L$	262	$\pm 12$
<b>H560</b> (SW B1.0 or higher)	WBC	$\times 10^9/L$	9.16	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.57	$\pm 0.08$
	HGB	g/L	138	$\pm 2$
		g/dL	13.8	$\pm 0.2$
	MCV	fL	86.0	$\pm 2.0$
	PLT	$\times 10^9/L$	268	$\pm 12$
<b>H360</b>	WBC	$\times 10^9/L$	9.25	$\pm 0.20$
	RBC	$\times 10^{12}/L$	4.98	$\pm 0.08$
	HGB	g/L	142	$\pm 2$
		g/dL	14.2	$\pm 0.2$
	MCV	fL	92.0	$\pm 2.0$
	PLT	$\times 10^9/L$	257	$\pm 12$





## TRACEABILITY

Erba Lachema s.r.o., Karásek 1d, 621 00 Brno hereby certifies the traceability of the assigned values of the product listed below to a reference material.

### Assignment of Reference Values to Fresh Whole Blood

**Hematology Calibrator** values are traceable to standard reference methods.

Hematology analyzers in the Quality Assurance Laboratory of the Supplier are whole blood calibrated to values obtained using the following standard reference methods. Whole blood samples drawn from normal, healthy donors are collected in EDTA anticoagulant and analyzed within six hours of collection.

The **White Blood Cell (WBC)** and **Red Blood Cell (RBC)** are analyzed on a Coulter Counter Z series instrument. All counts are corrected for coincidence.

**Hemoglobin** is measured using the Clinical Laboratory Standards Institute (CLSI) recommended reagent for the hemoglobincyanide (cyanmethemoglobin) method<sup>(1)</sup>. Readings are made at 540 nm in a colorimeter/spectrophotometer calibrated according to CLSI H15-A3 and ICSH recommendations<sup>(1)</sup>.

The **hematocrit** (packed cell volume) is measured using plain glass microhematocrit tubes (not coated with anticoagulant) centrifuged for 5 minutes in a microhematocrit centrifuge according to the CLSI H7-A3 document<sup>(2)</sup>. No correction is made for trapped plasma.

**Platelets** are assayed using a hemocytometer and phase contrast optics.

### Determination of uncertainty

Uncertainty is an estimate of the range in which the true value of a reported result may occur.

The uncertainty associated with the calibration of the H360, H560 and ELite 580 analyzer using the ELite H CAL calibrator has been estimated by adding the following sources of uncertainty:

- Uncertainty of the equipment used to determine the reference values: flask, pipette, single aperture impedance counter (WBC, RBC), Hemocytometer by phase-contrast (PLT), spectrophotometer (HGB), and ruler (HCT).
- Uncertainty of the hematology analyzer when calibrating with the ELite H CAL.

**Table 1:** Assignment results and uncertainty of reference method

	Reference	WBC (10 <sup>9</sup> /L)	RBC (10 <sup>12</sup> /L)	HGB (g/L)	MCV (fL)	PLT (10 <sup>9</sup> /L)
H360	Calibrator	9.25	4.98	142	92.0	257
	Relative expansion Uncertainty %	2.1	0.3	0.5	0.4	4.2
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW A12.2 or higher; version A only)	Calibrator	8.87	4.59	138	88.5	262
	Relative expansion Uncertainty %	2.2	0.6	0.3	0.1	4.4
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
H560 (SW B1.0 or higher)	Calibrator	9.16	4.57	138	86.0	268
	Relative expansion Uncertainty %	2.6	0.5	0.4	0.2	4.3
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified
ELite 580 (SW A10.4 or higher)	Calibrator	9.13	4.52	139	87.6	253
	Relative expansion Uncertainty %	2.5	0.4	0.2	0.3	4.1
	Standard	≤4%	≤2%	≤2%	≤2%	≤9%
	Result	Qualified	Qualified	Qualified	Qualified	Qualified

The reported expanded uncertainty in Table 1 is based on a standard uncertainty multiplied by a coverage factor of k=2 providing a level of confidence of approximately 95%.

Technical Product Management

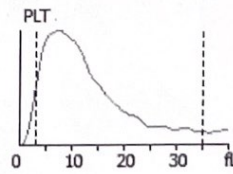
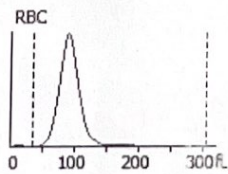
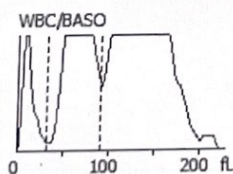
Erba Lachema s.r.o.

Brno 30.11.2022

## L-J QC Analysis

File No.: 5                                      Lot No.: EH2211N                                      Level: Normal  
 Operator: admin                                      Exp. Date: 2023/01/20                                      Run Time: 2023/01/14 11:22  
 Print Time: 2023/01/14 11:28                                      QC Mode: Whole Blood-CBC+DIFF                                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>8.52</b>	<b>6.90-8.90</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	59.5	50.0-66.0	%
3 Lym%	27.4	21.7-37.7	%
4 Mon%	5.4	1.4-11.4	%
5 Eos%	7.7	0.0-10.4	%
6 Bas%	71.1	63.2-79.2	%
7 Neu#	5.07	4.20-5.60	10 <sup>3</sup> /uL
8 Lym#	2.34	1.60-3.00	10 <sup>3</sup> /uL
9 Mon#	0.46	0.00-1.00	10 <sup>3</sup> /uL
10 Eos#	0.65	0.00-0.80	10 <sup>3</sup> /uL
11 Bas#	6.06	5.30-6.70	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>4.61</b>	<b>4.32-4.60</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	13.8	12.9-14.1	g/dL
14 HCT	41.6	35.5-42.5	%
15 MCV	90.1	80.5-90.5	fL
16 MCH	29.9	26.2-31.2	pg
17 MCHC	33.2	30.5-36.5	g/dL
18 RDW-CV	16.7	14.5-20.5	%
19 RDW-SD	56.1	42.3-62.3	fL
<b>20 PLT</b>	<b>235</b>	<b>180-260</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	10.1	7.0-13.0	fL
22 PDW-SD	11.4	9.9-15.9	fL
23 PDW-CV	16.1	13.6-19.6	%
24 PCT	0.237	0.135-0.335	%
25 P-LCR	27.4	19.8-35.8	%
26 P-LCC	64	42-92	10 <sup>9</sup> /L

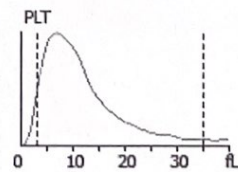
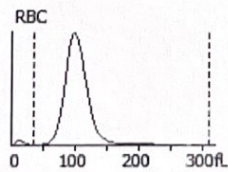
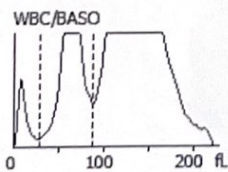


*[Handwritten Signature]*  
 7491122

## L-J QC Analysis

File No.: 4                      Lot No.: EH2211H                      Level: High  
 Operator: admin                      Exp. Date: 2023/01/20                      Run Time: 2023/01/14 11:20  
 Print Time: 2023/01/14 11:26                      QC Mode: Whole Blood-CBC+DIFF                      QC Sample ID:

Parameter	Result	Ref. Range	Unit
<b>1 WBC</b>	<b>18.32</b>	<b>15.07-20.07</b>	<b>10<sup>3</sup>/uL</b>
2 Neu%	68.4	58.7-72.7	%
3 Lym%	18.5	14.3-26.3	%
4 Mon%	7.2	0.8-12.8	%
5 Eos%	5.9	0.2-14.2	%
6 Bas%	81.9	72.3-88.3	%
7 Neu#	12.54	10.14-12.94	10 <sup>3</sup> /uL
8 Lym#	3.39	2.47-4.67	10 <sup>3</sup> /uL
9 Mon#	1.31	0.09-2.29	10 <sup>3</sup> /uL
10 Eos#	1.08	0.00-2.54	10 <sup>3</sup> /uL
11 Bas#	15.01	13.50-16.50	10 <sup>3</sup> /uL
<b>12 RBC</b>	<b>5.16</b>	<b>4.68-5.68</b>	<b>10<sup>6</sup>/uL</b>
13 HGB	17.3	8.7-24.7	g/dL
14 HCT	51.5	45.7-53.7	%
15 MCV	100.0	89.9-101.9	fL
16 MCH	33.6	29.8-34.8	pg
17 MCHC	33.6	30.7-36.7	g/dL
18 RDW-CV	16.6	13.8-19.8	%
19 RDW-SD	61.9	44.1-68.1	fL
<b>20 PLT</b>	<b>453</b>	<b>417-537</b>	<b>10<sup>3</sup>/uL</b>
21 MPV	9.2	7.1-13.1	fL
22 PDW-SD	9.8	9.7-15.7	fL
23 PDW-CV	15.0	13.3-19.3	%
24 PCT	0.419	0.282-0.682	%
25 P-LCR	21.9	18.8-34.8	%
26 P-LCC	99	93-163	10 <sup>9</sup> /L



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14/1/22